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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,179	02/01/2002	William A. Horne	480140.428C1	3580

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/066,179	HORNE ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/22/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant cancels claims 1-29 and adds new claims 30-32.

Accordingly, claims 30-32 are pending, and are examined in the instant application.

CONTINUATION DATA

The continuation data has been updated by the Examiner.

OBJECTION

1. Claim 32 is objected to for the use of the language "the 3' end of SEQ ID NO:2", which is a polypeptide.

For the purpose of compact prosecution, it is assumed that the 3' end of SEQ ID NO:2 recited in claim 32 means the carboxyl end of SEQ ID NO:2.

2. The abstract is objected to because the title of the abstract recites "Abstract of the invention". This objection could be obviated by amending the abstract to recite "Abstract of the disclosure".

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, NEW MATTER.

Claims 31-32 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention.

1. Claim 31 is drawn to an antibody that specifically binds to an isolated human Bad polypeptide encoded by a nucleotide sequence that has "greater than 85% nucleotide

identity to the nucleotide sequence shown in SEQ ID NO:1 as calculated by the BLAST algorithm".

The limitation of an antibody that specifically binds to an isolated human Bad polypeptide encoded by a nucleotide sequence that has "greater than 85% nucleotide identity to the nucleotide sequence shown in SEQ ID NO:1 as calculated by the BLAST algorithm" has no clear support in the specification and the claims as originally filed.

A review of the specification shows support for 1) generation of antibodies to human BAD amino acid sequence or fragments thereof (p.14, lines 14-16), 2) human Bad polypeptides that have an amino acid sequence substantially similar to SEQ ID NO:2 or functional equivalent thereof, or that are related but different by substitution of conserved and/or non-essential amino acids (p.9, second paragraph), and human Bad nucleic acid that has a nucleotide sequence subtanstially the same as SEQ IDNO:1 so as to selectively hybridize, or functional equivalent thereof (p.8). The subject matter claimed in claim 31 broadens the scope of the invention as originally disclosed in the specification.

2. Claim 32 is drawn to an antibody that specifically binds to human Bad polypeptide comprising a fragment of "no greater" than 95 contiguous amino acids of the 3' end of SEQ ID NO:2, wherein the fragment binds Bcl-XL or Bcl-2, and wherein the fragment contains "at least" one amino acid that differs when aligned with SEQ ID NO:3.

The limitation of "no great r than" 95 contiguous amino acids, or the limitation "at least" one amino acid that differs when aligned with SEQ ID NO:3 has no clear support in the specification and the claims as originally filed.

A review of the specification shows support for 1) generation of antibodies to human BAD amino acid sequence or fragments thereof (p.14, lines 14-16), 2) two partial cDNAs encoding 95 amino acids of the 3' end of Bad (p. 27, lines 114-16), 3) alignment of human Bad polypeptide of SEQ ID NO:2 with mouse Bad polypeptide of SEQ ID NO:3 (figure 2).

Further, the limitation that the 95 amino acid fragment binds Bcl-XL or Bcl-2 has no clear support in the specification and the claims as originally filed.

A review of the specification discloses support for isolation of two partial cDNAs encoding 95 amino acids of the 3' end of Bad (p. 27, lines 114-16), and support for using full length human BAD sequence to assess binding of human BAD polypeptide to Bcl-XL or Bcl-2 in a yeast two-hybrid system (Example 29 on pages 29-31, and in particular, page 29, lines 19-20, and line 28 bridging line 1 of page 30).

The subject matter claimed in claim 32 broadens the scope of the invention as originally disclosed in the specification.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art

can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

Claim 31 is rejected under 35 USC 112, first paragraph.

Claim 31 is drawn to an antibody that specifically binds to an isolated human Bad polypeptide encoded by a nucleotide sequence that has "greater than 85% nucleotide identity to the nucleotide sequence shown in SEQ ID NO:1 as calculated by the BLAST algorithm".

Claim 31 encompasses an antibody that specifically binds to a polypeptide encoded by a variant of SEQ ID NO:1, with unknown structure and function.

The findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are clearly relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define

> any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed

correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

Thus, the instant specification may provide an adequate written description of the polypeptide encoded by a nucleotide sequence that has greater than 85% identity with SEQ ID NO:1, to which the claimed antibody binds to, per Lilly by structurally describing a representative number said polypeptides, or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe the polypeptide encoded by a nucleotide sequence that has greater than 85% identity with SEQ ID NO:1, to which the claimed antibody specifically binds, required to practice claim 31 in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of any polypeptide encoded by a nucleotide sequence that has greater than 85% identity with SEQ ID NO:1 other than SEQ ID NO:2, nor does the specification provide any partial common structure of such the polypeptide encoded by a nucleotide sequence that has greater than 85% identity with SEQ ID NO:1, nor any physical or chemical characteristics of the polypeptide encoded by a nucleotide sequence that has greater than 85% identity with SEQ ID NO:1, other than SEQ ID

NO:2, nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses a single polypeptide, SEQ ID NO:2, this does not provide a description of the polypeptide encoded by a nucleotide sequence that has greater than 85% identity with SEQ ID NO:1, to which the claimed antibody binds to, that would satisfy the standard set out in Enzo.

The specification also fails to describe the polypeptide encoded by a nucleotide sequence that has greater than 85% identity with SEQ ID NO:1, to which the claimed antibody specifically binds, by the test set out in Lilly. The specification describes only a single polypeptide, SEQ ID NO:2. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, since the specification does not provide an adequate written description of a polypeptide encoded by a nucleotide sequence that has greater than 85% identity with SEQ ID NO:1, to which the antibody specifically binds, the specification also does not provide an adequate written description of the antibody that specifically binds to a polypeptide encoded by a nucleotide sequence that has greater than 85% identity with SEQ ID NO:1, that is required to practice the claimed invention.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

1. Claim 31 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody that specifically binds to an isolated human Bad ppolypeptide encoded by the nucleotide sequence of SEQ ID NO:1, **does not reasonably provide enablement for an antibody that specifically binds to an isolated human Bad polypeptide encoded by a nucleotide sequence that has "greater than 85% nucleotide identity to the nucleotide sequence shown in SEQ ID NO:1 as calculated by the BLAST algorithm".** The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 31 is drawn to an antibody that specifically binds to an isolated human Bad polypeptide encoded by a nucleotide sequence that has "greater than 85% nucleotide identity to the nucleotide sequence shown in SEQ ID NO:1 as calculated by the BLAST algorithm".

Claim 31 encompasses an antibody that specifically binds to a polypeptide encoded by a variant of SEQ ID NO:1, with unknown structure and function.

The scope of the claim 31 includes antibodies that specifically bind to numerous structural variants. Applicants have not shown how to make and use the polypeptide variants which have the properties of the polypeptide of SEQ ID NO:2, as that which is being disclosed.

The claim reads on an antibody that specifically binds to a variant polypeptide encoded by a variant of the nucleotide sequence SEQ ID NO:1, wherein said polypeptide has any type of substitution besides conservative substitution, at any amino

acid, throughout the length of the polypeptide, as well as insertions and deletions. The specification and the claim do not place any limit on which amino acid to be subjected to conservative or non-conservative substitution, the type of substitution besides conservative substitution, nor the type of amino acids replacing the original amino acids. Thus the scope of the claim includes antibodies to polypeptides encoded by nucleotide sequences having numerous structural variants. The specification and the claims do not provide any guidance as to which original amino acid(s) to be substituted, or to which type of substitution besides conservative substitution, or which amino acids could be deleted or inserted in the encoded polypeptide, so that the encoded polypeptide to which the claimed antibody binds could have the same characteristics as SEQ ID NO:2.

One cannot extrapolate the teaching in the specification to the scope of the claim because one cannot predict that the variants of SEQ ID NO:2 would have properties related to that of SEQ ID NO:2. It is well known in the art that protein chemistry is probably one of the most unpredictable areas of biotechnology and that even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristic of a protein. For example, Bowie et al (Science, 1990, 257 : 1306-1310) teach that an amino acid sequence encodes a message that determine the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function and carry out the instruction of the genome and further teaches that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is

extremely complex (col.1, p.1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitution can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (col.2, p.1306). The 3-dimensional folding of the native molecule however is of significant importance in an antibody response, because epitopes of an antibody could be linear and/or conformational. For example, Roger, I et al, 1988, Bioscience Reports, 8(4): 359-368, teach that several epitopes of p85 glycoprotein are conformational determinants and are destroyed by reduction of said glycoprotein (abstract). The references thus demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification will often dramatically affect the characteristics or three dimensional structure of a protein, and consequently the binding and characteristics of the antibodies specific for said protein.

The specification does not disclose how to make the variant polypeptides to which the claimed antibodies bind to, such that they would have the properties as claimed.

It is noted that MPEP 2164.03 teaches that "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The amount of guidance or direction refers to that

information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature ot the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to explicitly stated in the specification. In constrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order to be enabling."

Given the unpredictability that the polypeptide variants, to which the claimed antibodies bind, would have the property or function of SEQ ID NO:2 , the lack of adequate disclosure in the specification on how to make such variants, and in view of the complex nature of the claimed invention, and little is known in the art about the claimed invention, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

REJECTION UNDER 35 USC 102(e)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the

requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 30-32 are rejected under 35 USC 102(e) as being anticipated by US 5,622,852

Claims 30-32 are drawn to:

1) an antibody that specifically binds to an isolated human Bad polypeptide, comprising the amino acid sequence shown in SEQ ID NO:2 (claim 30),

2) an antibody that specifically binds to an isolated human Bad polypeptide encoded by a nucleotide sequence that has greater than 85% nucleotide identity to the nucleotide sequence shown in SEQ ID NO:1 as calculated by the BLAST algorithm (claim 31), and

3) an antibody that specifically binds to human Bad polypeptide comprising a fragment of no greater than 95 contiguous amino acids of the 3' end of SEQ ID NO:2, wherein the fragment binds Bcl-XL or Bcl-2, and wherein the fragment contains at least one amino acid that differs when aligned with SEQ ID NO:3 (claim 32).

For the purpose of compact prosecution, it is assumed that the 3' end of SEQ ID NO:2 recited in claim 32 means the carboxyl end of SEQ ID NO:2.

It is noted that the polypeptide of claim 32 reads on the polypeptide of SEQ ID NO:2, and that "specifically bind to" could be reasonably interpreted as either high or low specific, or specific to an epitope.

US 5,622,852 teaches a polyclonal antibody to a mouse BAD polypeptide and fragments thereof (column 36, lines 21-24), and antibodies raised against a Bad sequence and bind to a Bad protein, such as the native mouse BAD sequence as shown in figure 2, a native human Bad polypeptide, or a polypeptide comprising a Bad epitope (column 36, lines 39-44). US 5,622,852 teaches BH1 region from amino acid 137 to amino acid 160 and BH2 region from amino acid 182 to amino acid 197 of the mouse BAD polypeptide (figure 5 and column 6, second paragraph).

The mouse BAD polypeptide sequence taught by US 5,622,852 is 75% similar to SEQ ID NO:2 of the claimed invention, from amino acid 1 to amino acid 168, as shown in MPSRCH sequence similarity search (MPSRCH search report, 2003, us-10-066-179-2.rai, page 4).

The polyclonal antibody against the mouse BAD polypeptide or a fragment thereof, taught by US 5,622,852 would specifically bind to the polypeptide of SEQ ID NO:2 of the claimed invention, because it is well known in the art that different components or subsets of a polyclonal antibody would bind to multiple sites of a protein, as taught by Paul, W E, ed, 1993, Fundamental Immunol, 3rd ed, Raven Press, NY, p.460, and because the mouse BAD polypeptide taught by US 5,622,852 has several

stretches of several contiguous amino acids that are the same as those of SEQ ID NO:2 of the claimed invention (see MPSRCH search report), wherein said stretches of amino acids would share at least some of the epitopes of subsets of the polyclonal antibody against the mouse BAD polypeptide or a fragment thereof, taught by US 5,622,852.

Further, subsets of the polyclonal antibody against the mouse BAD polypeptide or a fragment thereof, such as the BH1 or BH2 region, taught by US 5,622,852 would specifically bind to human Bad polypeptide comprising a fragment of no greater than 95 contiguous amino acids of the 3' end of SEQ ID NO:2, wherein the fragment binds Bcl-XL or Bcl-2, and wherein the fragment contains at least one amino acid that differs when aligned with SEQ ID NO:3. As shown by MPSRCH search report, the mouse BAD polypeptide and SEQ ID NO:2 of the claimed invention share a fragment of no greater than 95 amino acids at the carboxyl end of the sequences, encompassing amino acids 103-124 of SEQ ID NO:2, or the BH3 domain, which is necessary for binding to Bcl-2 or Bcl-XL, as taught by Ottilie et al, 1997, J Biol Chem, 272(49): 30866-30872, and having the same conserved amino acids L and DE in said BH3 domain. Thus subsets of a polyclonal clonal antibody to the BAD mouse polypeptide or a fragment thereof, taught by US 5,622,852 would bind to at least some of the shared epitopes in said fragment of no greater than 95 contiguous amino acids bound by the claimed antibody.

The reference does not specifically teach an antibody that specifically binds to the human BAD polypeptide of SEQ ID NO:2, or an isolated human Bad polypeptide encoded by a nucleotide sequence that has greater than 85% nucleotide identity to the nucleotide sequence shown in SEQ ID NO:1 as calculated by the BLAST algorithm, or

an antibody that specifically binds to human Bad polypeptide comprising a fragment of no greater than 95 contiguous amino acids of the 3' end of SEQ ID NO:2, wherein the fragment binds Bcl-XL or Bcl-2, and wherein the fragment contains at least one amino acid that differs when aligned with SEQ ID NO:3. However, the claimed antibody appears to be the same as the prior art polyclonal antibody. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable diffrences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, YVONNE EYLER can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

PATENT EXAMINER

February 03, 2004